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EXAMINER
ASTORINO, M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3736 | |

DATE MAILED: 04/27/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/070,677

Applicant(s)

Aria et al.

Examiner

Michael Astorino

Group Art Unit

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☒ Responsive to communication(s) filed on Apr 30, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-120 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-39, 41, 43, 45-47, 51-59, 62-68, 71-84, 87, 88, 112-116, and 118-120 are rejected.

☒ Claim(s) 40, 42, 44, 48-50, 60, 61, 69, 70, 85, 86, 89-93, and 117 is/are objected to.

☒ Claims 94-112 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-93 and 113-120, drawn to an analyte monitoring system, classified in class 600, subclass 345.
 - II. Claims 94-103, drawn to an insertion kit, classified in class 600, subclass 300.
 - III. Claims 104-107, drawn to method of using an electrochemical sensor, classified in class 600, subclass 345.
 - IV. Claims 108, drawn to method of detecting failure in a analyte responsive sensor, classified in class 600, subclass 345.
 - V. Claims 109-112, drawn to a method of calibrating, classified in class 600, subclass 300.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions.
3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different process.

4. Inventions I and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used in a different process.

5. Inventions I and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used in a different process.

6. Because these inventions are distinct for the reasons given above and the search required for Group I-V is not required for Group , restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Bruce Black on 4/22/99 a provisional election was made without traverse to prosecute the invention of I, claims 1-93 and 113-120. Affirmation of this election must be made by applicant in replying to this Office action. Claims 94-112 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Drawings

9. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-39 and 80-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 1 recites the limitation "the sensor" in lines 5 and 7. There is insufficient antecedent basis for this limitation in the claim.

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13. Claims 80-84 recites the limitation "the one or more physiological characteristics" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

15. Claims 1-10, 17-19, 20-22, 24-28, 41, 43, 45-47, 51-59, 62-68, 71-78, 87-88, 113-116, and 118-120 are rejected under 35 U.S.C. 102(e) as being anticipated by Schulman et al..

Regarding claims 1-10, 41, 43, 45-47, 51-59, 71, and 113-115, 118-120, Schulman discloses a housing and mounting unit (110) adapted for placement on the skin, an electrochemical sensor (106, 108) with conductive contacts, and a transmitter (142), and a display coupled to a receiver (34, column 12, lines 59-67). It is the examiner's position that is obvious to maintain a water resistant seal between the base and cover so that the electrical does not short.

Regarding claims 17-19, Schulman discloses a battery (144) in the housing. It is the examiner's position that any battery of any kind is removable from a housing.

Regarding claims 20-22, 24-28, 68, 72-78 and 116, Schulman discloses an alarm (column 16) and an audible alarm (block 282). Schulman discloses an audible and a visual alarm.

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Although Schulman does not disclose an electrical shock, vibration or increasing audible alarm it is obvious to one in the art that the disclosed alarm indication means is obvious in the art.

Regarding claim 62-63, it is the examiner's position that any device is portable and can be worn on a piece of clothing.

Regarding claims 64-67, Schulman discloses in figure 1, an electric power source with a monitor.

Regarding claim 87-88, Schulman discloses a temperature measurement device (90).

Allowable Subject Matter

16. Claims 11-16, 20-39, 40, 42, 44, 48-50, 60-61, 69-70, 79, 80-86, 89-93 and 117 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gross et al. ('375, '622 and '420), DeMarzo ('552) and Worthington ('715).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Astorino whose telephone number is (703) 306-9067.

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M. Astorino

April 26, 1999



CARY O'CONNOR
SUPERVISORY PATENT EXAMINER
GROUP 3736